General

Guideline Title

The diagnosis and management of acute otitis media.

Bibliographic Source(s)

Lieberthal AS, Carroll AE, Chonmaitree T, Ganiats TG, Hoberman A, Jackson MA, Joffe MD, Miller DT, Rosenfeld RM, Sevilla XD, Schwartz RH, Thomas PA, Tunkel DE. The diagnosis and management of acute otitis media. Pediatrics. 2013 Mar;131(3):e964-99. [275 references] PubMed

Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Pediatrics 2004 May;113(5):1451-65.

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

Regulatory Alert

FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

- December 14, 2016 – General anesthetic and sedation drugs : The U.S. Food and Drug Administration (FDA) is warning that repeated or lengthy use of general anesthetic and sedation drugs during surgeries or procedures in children younger than 3 years or in pregnant women during their third trimester may affect the development of children's brains. Consistent with animal studies, recent human studies suggest that a single, relatively short exposure to general anesthetic and sedation drugs in infants or toddlers is unlikely to have negative effects on behavior or learning. However, further research is needed to fully characterize how early life anesthetic exposure affects children's brain development.

Recommendations

Major Recommendations

Definitions for the quality of the evidence (A-D, X) and the strength of the recommendation (strong recommendation, recommendation, option) are provided at the end of the "Major Recommendations" field.

Key Action Statement 1A

Clinicians should diagnose acute otitis media (AOM) in children who present with moderate to severe bulging of the tympanic membrane (TM) *or* new onset of otorrhea not due to acute otitis externa. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 1A

- Aggregate evidence quality: Grade B
- Benefits: Identify a population of children most likely to benefit from intervention. Avoid unnecessary treatment of those without highly certain acute otitis media (AOM). Promote consistency in diagnosis.
- Risks, harms, cost: May miss AOM that presents with a combination of mild bulging, intense erythema, or otalgia that may not necessarily represent less severe disease and may also benefit from intervention.
- Benefits-harms assessment: Preponderance of benefit
- Value judgments: Identification of a population of children with highly certain AOM is beneficial. Accurate, specific diagnosis is helpful to the individual patient. Modification of current behavior of overdiagnosis is a goal. Increased specificity is preferred even as sensitivity is lowered.
- Intentional vagueness: By using stringent diagnostic criteria, the tympanic membrane (TM) appearance of less severe illness that might be early AOM has not been addressed.
- Role of patient preferences: None
- Exclusions: None
- Strength: Recommendation
- Notes: Tympanocentesis studies confirm that using these diagnostic findings leads to high levels of isolation of pathogenic bacteria. Evidence is extrapolated from treatment studies that included tympanocentesis.

Key Action Statement 1B

Clinicians should diagnose AOM in children who present with mild bulging of the TM *and* recent (less than 48 hours) onset of ear pain (holding, tugging, rubbing of the ear in a nonverbal child) or intense erythema of the TM. (Evidence Quality: Grade C, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 1B

- Aggregate evidence quality: Grade C
- Benefits: Identify AOM in children when the diagnosis is not highly certain.
- Risks, harms, cost: Overdiagnosis of AOM. Reduced precision in diagnosis.
- Benefits-harms assessment: Benefits greater than harms
- Value judgments: None
- Intentional vagueness: Criteria may be more subjective.
- Role of patient preferences: None
- Exclusions: None
- Strength: Recommendation
- Notes: Recent onset of ear pain means within the past 48 hours.

Key Action Statement 1C

Clinicians should not diagnose AOM in children who do not have middle ear effusion (MEE) (based on pneumatic otoscopy and/or tympanometry). (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 1C

- Aggregate evidence quality: Grade B
- Benefits: Reduces overdiagnosis and unnecessary treatment. Increases correct diagnosis of other conditions with symptoms that otherwise might be attributed to AOM. Promotes the use of pneumatic otoscopy and tympanometry to improve diagnostic accuracy.
- Risks, harms, cost: Cost of tympanometry. Need to acquire or reacquire skills in pneumatic otoscopy and tympanometry for some clinicians.
- Benefits-harms assessment: Preponderance of benefit
- Value judgments: AOM is overdiagnosed, often without adequate visualization of the TM. Early AOM without effusion occurs, but the risk

of over-diagnosis supersedes that concern.
- Intentional vagueness: None
- Role of patient preferences: None
- Exclusions: Early AOM evidenced by intense erythema of the TM
- Strength: Recommendation

Key Action Statement 2

The management of AOM should include an assessment of pain. If pain is present, the clinician should recommend treatment to reduce pain. (Evidence Quality: Grade B, Rec. Strength: Strong Recommendation)

Key Action Statement Profile: KAS 2

- Aggregate evidence quality: Grade B
- Benefits: Relieves the major symptom of AOM.
- Risks, harms, cost: Potential medication adverse effects. Variable efficacy of some modes of treatment.
- Benefits-harms assessment: Preponderance of benefit
- Value judgments: Treating pain is essential whether or not antibiotics are prescribed.
- Intentional vagueness: Choice of analgesic is not specified.
- Role of patient preferences: Parents may assist in the decision as to what means of pain relief they prefer.
- Exclusions: Topical analgesics in the presence of a perforated TM
- Strength: Strong Recommendation

Key Action Statement 3A

Severe AOM

The clinician should prescribe antibiotic therapy for AOM (bilateral or unilateral) in children 6 months and older with severe signs or symptoms (i.e., moderate or severe otalgia or otalgia for at least 48 hours or temperature 39°C [102.2°F] or higher). (Evidence Quality: Grade B, Rec. Strength: Strong Recommendation)

Key Action Statement Profile: KAS 3A

- Aggregate evidence quality: Grade B
- Benefits: Increased likelihood of more rapid resolution of symptoms. Increased likelihood of resolution of AOM.
- Risks, harms, cost: Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. Cost of antibiotics.
- Benefits-harms assessment: Preponderance of benefit over harm
- Value judgments: None
- Role of patient preference: None
- Intentional vagueness: None
- Exclusions: None
- Strength: Strong Recommendation

Key Action Statement 3B

Nonsevere Bilateral AOM in Young Children

The clinician should prescribe antibiotic therapy for bilateral AOM in children younger than 24 months without severe signs or symptoms (i.e., mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 3B

- Aggregate evidence quality: Grade B
- Benefits: Increased likelihood of more rapid resolution of symptoms. Increased likelihood of resolution of AOM.
- Risks, harms, cost: Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. Cost of antibiotics.
- Benefits-harms assessment: Preponderance of benefit over harm
- Value judgments: None

- Role of patient preference: None
- Intentional vagueness: None
- Exclusions: None
- Strength: Recommendation

Key Action Statement 3C

Nonsevere Unilateral AOM in Young Children

The clinician should either prescribe antibiotic therapy *or* offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for unilateral AOM in children 6 months to 23 months of age without severe signs or symptoms (i.e., mild otalgia for less than 48 hours and temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 3C

- Aggregate evidence quality: Grade B
- Benefits: Moderately increased likelihood of more rapid resolution of symptoms with initial antibiotics. Moderately increased likelihood of resolution of AOM with initial antibiotics.
- Risks, harms, cost: Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. Cost of antibiotics.
- Benefits-harms assessment: Moderate degree of benefit over harm
- Value judgments: Observation becomes an alternative as the benefits and harms approach balance.
- Role of patient preference: Joint decision-making with the family is essential before choosing observation.
- Intentional vagueness: Joint decision-making is highly variable from family to family.
- Exclusions: None
- Strength: Recommendation
- Note: In the judgment of 1 Subcommittee member (AH), antimicrobial treatment of these children is preferred because of a preponderance of benefit over harm. AH did not endorse Key Action Statement 3C.

Key Action Statement 3D

Nonsevere AOM in Older Children

The clinician should either prescribe antibiotic therapy or offer observation with close follow-up based on joint decision-making with the parent(s)/caregiver for AOM (bilateral or unilateral) in children 24 months or older without severe signs or symptoms (i.e., mild otalgia for less than 48 hours, temperature less than 39°C [102.2°F]). When observation is used, a mechanism must be in place to ensure follow-up and begin antibiotic therapy if the child worsens or fails to improve within 48 to 72 hours of onset of symptoms. (Evidence Quality: Grade B, Rec Strength: Recommendation)

Action Statement Profile: KAS 3D

- Aggregate evidence quality: Grade B
- Benefits: *Initial antibiotic treatment*: Slightly increased likelihood of more rapid resolution of symptoms; slightly increased likelihood of resolution of AOM. *Initial observation*: Decreased use of antibiotics; decreased adverse effects of antibiotics; decreased potential for development of bacterial resistance.
- Risks, harms, cost: Initial antibiotic treatment: Adverse events attributable to antibiotics such as diarrhea, rashes, and allergic reactions. Overuse of antibiotics leads to increased bacterial resistance. *Initial observation*: Possibility of needing to start antibiotics in 48 to 72 hours if the patient continues to have symptoms. Minimal risk of adverse consequences of delayed antibiotic treatment. Potential increased phone calls and doctor visits.
- Benefits-harms assessment: Slight degree of benefit of initial antibiotics over harm.
- Value judgments: Observation is an option as the benefits and harms approach balance.
- Role of patient preference: Joint decision-making with the family is essential before choosing observation.
- Intentional vagueness: Joint decision-making is highly variable from family to family.
- Exclusions: None
- Strength: Recommendation

Key Action Statement 4A

Clinicians should prescribe amoxicillin for AOM when a decision to treat with antibiotics has been made *and* the child has not received amoxicillin in the past 30 days *or* the child does not have concurrent purulent conjunctivitis *or* the child is not allergic to penicillin. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 4A

- Aggregate evidence quality: Grade B
- Benefits: Effective antibiotic for most children with AOM. Inexpensive, safe, acceptable taste, narrow antimicrobial spectrum.
- Risks, harms, cost: Ineffective against β-lactamase–producing organisms. Adverse effects of amoxicillin.
- Benefits-harms assessment: Preponderance of benefit
- Value judgments: Better to use a drug that has reasonable cost, has an acceptable taste, and has a narrow antibacterial spectrum.
- Intentional vagueness: The clinician must determine whether the patient is truly penicillin allergic.
- Role of patient preferences: Should be considered if previous bad experience with amoxicillin
- Exclusions: Patients with known penicillin allergy
- Strength: Recommendation

Key Action Statement 4B

Clinicians should prescribe an antibiotic with additional β-lactamase coverage for AOM when a decision to treat with antibiotics has been made *and* the child has received amoxicillin in the last 30 days *or* has concurrent purulent conjunctivitis, *or* has a history of recurrent AOM unresponsive to amoxicillin. (Evidence Quality: Grade C, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 4B

- Aggregate evidence quality: Grade C
- Benefits: Successful treatment of β-lactamase–producing organisms.
- Risks, harms, cost: Cost of antibiotic. Increased adverse effects.
- Benefits-harms assessment: Preponderance of benefit
- Value judgments: Efficacy is more important than taste.
- Intentional vagueness: None
- Role of patient preferences: Concern regarding side effects and taste
- Exclusions: Patients with known penicillin allergy
- Strength: Recommendation

Key Action Statement 4C

Clinicians should reassess the patient if the caregiver reports that the child's symptoms have worsened or failed to respond to the initial antibiotic treatment within 48 to 72 hours and determine whether a change in therapy is needed. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Key Action Statement Profile: KAS 4C

- Aggregate evidence quality: Grade B
- Benefits: Identify children who may have AOM caused by pathogens resistant to previous antibiotics.
- Risks, harms, cost: Cost. Time for patient and clinician to make change. Potential need for parenteral medication.
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: None
- Intentional vagueness: "Reassess" is not defined. The clinician may determine the method of assessment.
- Role of patient preferences: Limited
- Exclusions: Appearance of TM improved
- Strength: Recommendation

Key Action Statement 5A

Clinicians should *NOT* prescribe prophylactic antibiotics to reduce the frequency of episodes of AOM in children with recurrent AOM. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Action Statement Profile: KAS 5A

- Aggregate evidence quality: Grade B
- Benefits: No adverse effects from antibiotic. Reduces potential for development of bacterial resistance. Reduced costs.
- Risks, harms, cost: Small increase in episodes of AOM.
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: Potential harm outweighs the potential benefit.
- Intentional vagueness: None
- Role of patient preferences: Limited
- Exclusions: Young children whose only alternative would be tympanostomy tubes
- Strength: Recommendation

Key Action Statement 5B

Clinicians may offer tympanostomy tubes for recurrent AOM (3 episodes in 6 months or 4 episodes in 1 year with 1 episode in the preceding 6 months). (Evidence Quality: Grade B, Rec. Strength: Option)

Action Statement Profile: KAS 5B

- Aggregate evidence quality: Grade B
- Benefits: Decreased frequency of AOM. Ability to treat AOM with topical antibiotic therapy.
- Risks, harms, cost: Risks of anesthesia or surgery. Cost. Scarring of TM, chronic perforation, cholesteatoma. Otorrhea.
- Benefits-harms assessment: Equilibrium of benefit and harm
- Value judgments: None
- Intentional vagueness: Option based on limited evidence
- Role of patient preferences: Joint decision of parent and clinician
- Exclusions: Any contraindication to anesthesia and surgery
- Strength: Option

Key Action Statement 6A

Pneumococcal Vaccine

Clinicians should recommend pneumococcal conjugate vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices of the Centers for Disease Control and Prevention, American Academy of Pediatrics (AAP), and American Academy of Family Physicians (AAFP). (Evidence Quality: Grade B, Rec. Strength: Strong Recommendation)

Action Statement Profile: KAS 6A

- Aggregate evidence quality: Grade B
- Benefits: Reduced frequency of AOM attributable to vaccine serotypes. Reduced risk of serious pneumococcal systemic disease.
- Risks, harms, cost: Potential vaccine side effects. Cost of vaccine.
- Benefits-harms assessment: Preponderance of benefit
- Value judgments: Potential vaccine adverse effects are minimal.
- Intentional vagueness: None
- Role of patient preferences: Some parents may choose to refuse the vaccine.
- Exclusions: Severe allergic reaction (e.g., anaphylaxis) to any component of pneumococcal vaccine or any diphtheria toxoid-containing vaccine
- Strength: Strong Recommendation

Key Action Statement 6B

Influenza Vaccine

Clinicians should recommend annual influenza vaccine to all children according to the schedule of the Advisory Committee on Immunization Practices, AAP, and AAFP. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Action Statement Profile: KAS 6B

- Aggregate evidence quality: Grade B
- Benefits: Reduced risk of influenza infection. Reduction in frequency of AOM associated with influenza
- Risks, harms, cost: Potential vaccine adverse effects. Cost of vaccine. Requires annual immunization.
- Benefits-harms assessment: Preponderance of benefit
- Value judgments Potential vaccine adverse effects are minimal.
- Intentional vagueness: None
- Role of patient preferences: Some parents may choose to refuse the vaccine.
- Exclusions: See the Centers for Disease Control and Prevention (CDC) guideline on contraindications (http://www.cdc.gov/flu/professionals/acip/shouldnot.htm).
- Strength: Recommendation

Key Action Statement 6C

Clinicians should encourage exclusive breastfeeding for at least 6 months. (Evidence Quality: Grade B, Rec. Strength: Recommendation)

Action Statement Profile: KAS 6C

- Aggregate evidence quality: Grade B
- Benefits: May reduce the risk of early AOM. Multiple benefits of breastfeeding unrelated to AOM.
- Risk, harm, cost: None
- Benefit-harm assessment: Preponderance of benefit
- Value judgments: The intervention has value unrelated to AOM prevention.
- Intentional vagueness: None
- Role of patient preferences: Some parents choose to feed formula.
- Exclusions: None
- Strength: Recommendation

Key Action Statement 6D

Clinicians should encourage avoidance of tobacco smoke exposure. (Evidence Quality: Grade C, Rec. Strength: Recommendation)

Action Statement Profile: KAS 6D

- Aggregate evidence quality: Grade C
- Benefits: May reduce the risk of AOM.
- Risks, harms, cost: None
- Benefits-harms assessment: Preponderance of benefit
- Value judgments: Avoidance of tobacco exposure has inherent value unrelated to AOM.
- Intentional vagueness: None
- Role of patient preferences: Many parents/caregivers choose not to stop smoking. Some also remain addicted, and are unable to quit smoking.
- Exclusions: None
- Strength: Recommendation

Definitions:

Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified	Clinicians would be prudent to follow a

Statement	Definition	Implication
	circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	recommendation but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

Evidence Quality

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well-designed randomized controlled trials (RCTs) or diagnostic studies on relevant population	Strong recommendation	Option
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies	Recommendation/Strong Recommendation	
C. Observational studies (case-control and cohort design)	Recommendation	
D. Expert opinion, case reports, reasoning from first principles	Option	No Recommendation
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Recommendation/Strong Recommendation	

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Acute otitis media

Guideline Category

Diagnosis

Prevention

Treatment

Clinical Specialty

Allergy and Immunology

Family Practice

Infectious Diseases

Otolaryngology

Pediatrics

Preventive Medicine

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide recommendations to primary care clinicians for the management of children from 6 months through 12 years of age with uncomplicated acute otitis media (AOM)

Target Population

Children from 6 months through 12 years of age with uncomplicated acute otitis media seen in primary care settings

Interventions and Practices Considered

1. Diagnosis of acute otitis media (AOM) for:
    - Children with moderate to severe bulging of the tympanic membrane (TM) or new onset of otorrhea not due to acute otitis externa
    - Children with mild bulging of the TM and recent onset (less than 48 hours) of ear pain or intense erythema of the TM
2. Assessment of pain
3. Treatment
    - Antibiotic therapy, amoxicillin, additional β-lactamase coverage
    - Observation with close follow-up
4. Reassessment if patient does not respond to therapy in 48 to 72 hours
5. Tympanostomy tubes for recurrent AOM
6. Preventive measures
    - Pneumococcal conjugate vaccine
    - Annual influenza vaccine
    - Exclusive breastfeeding for 6 months (in infants)
    - Avoidance of tobacco exposure

Note: Prophylactic antibiotics to reduce the frequency of episodes of AOM were considered but not recommended.

Major Outcomes Considered

- Pain and/or fever
- Time to resolution of symptoms/time to treatment failure
- Symptom burden over time

- Parent satisfaction with acute otitis media (AOM) care
- AOM failure and recurrence
- Nasopharyngeal carriage of *Streptococcus pneumoniae* strains resistant to antibiotics after treatment
- Adverse effects of antibiotics

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Agency for Healthcare Research and Quality (AHRQ) Evidence Report

In preparing for the 2004 American Academy of Pediatrics (AAP) guidelines, the AHRQ funded and conducted an exhaustive review of the literature on diagnosis and management of acute otitis media (AOM). In 2008, the AHRQ and the Southern California Evidence-Based Practice Center began a similar process of reviewing the literature published since the 2001 AHRQ report. The AAP again partnered with AHRQ and the Southern California Evidence-Based Practice Center to develop the evidence report, which served as a major source of data for these practice guideline recommendations.

For the 2010 review (see the "Availability of Companion Documents" field), searches of PubMed and the Cochrane Database of Systematic Reviews, Cochrane Central Register of Controlled Trials, and Education Resources Information Center were conducted by using the same search strategies used for the 2001 report for publications from 1998 through June 2010. Additional terms or conditions not considered in the 2001 review (recurrent OM, new drugs, and heptavalent pneumococcal vaccine) were also included. The Web of Science was also used to search for citations of the 2001 report and its peer-reviewed publications. Titles were screened independently by 2 pediatricians with experience in conducting systematic reviews.

For the question pertaining to diagnosis, efficacy, and safety, the search was primarily for clinical trials. For the question pertaining to the effect of pneumococcal conjugate vaccine (PCV7) on epidemiology and microbiology, the group searched for trials that compared microbiology in the same populations before and after introduction of the vaccine or observational studies that compared microbiology across vaccinated and unvaccinated populations.

AAP Methods

New literature on otitis media (OM) is continually being published. Although the systematic review performed by AHRQ could not be replicated with new literature, members of the Subcommittee on Diagnosis and Management of Acute Otitis Media reviewed additional articles. PubMed was searched by using the single search term "acute otitis media," approximately every 6 months from June 2009 through October 2011 to obtain new articles.

Number of Source Documents

Seventy-two articles that met the predetermined inclusion and exclusion criteria were reviewed in detail.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Evidence Quality

Evidence Quality	Preponderance of Benefit or Harm	Balance of Benefit and Harm
A. Well-designed randomized controlled trials (RCTs) or diagnostic studies on relevant population	Strong recommendation	Option
B. RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies	Recommendation/Strong Recommendation	
C. Observational studies (case-control and cohort design)	Recommendation	
D. Expert opinion, case reports, reasoning from first principles	Option	No Recommendation
X. Exceptional situations where validating studies cannot be performed and there is a clear preponderance of benefit or harm	Recommendation/Strong Recommendation	

Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Agency for Healthcare Research and Quality (AHRQ) Evidence Report (see the "Availability of Companion Documents" field)

Investigators abstracted data into standard evidence tables, with accuracy checked by a second investigator. Studies were quality-rated by 2 investigators by using established criteria. For randomized controlled trials, the Jadad criteria were used. Quality Assessment Tool for Diagnostic Accuracy Studies (QUADAS) criteria were used to evaluate the studies that pertained to diagnosis. Grading of Recommendations Assessment, Development and Evaluation (GRADE) criteria were applied to pooled analyses. Data abstracted included parameters necessary to define study groups, inclusion/exclusion criteria, influencing factors, and outcome measures. Some of the data for analysis were abstracted by a biostatistician and checked by a physician reviewer. A sequential resolution strategy was used to match and resolve the screening and review results of the 2 pediatrician reviewers.

For the assessment of treatment efficacy, pooled analyses were performed for comparisons for which 3 or more trials could be identified. Studies eligible for analyses of questions pertaining to treatment efficacy were grouped for comparisons by treatment options. Each comparison consisted of studies that were considered homogeneous across clinical practice. Because some of the key questions were addressed in the 2001 evidence report, studies identified in that report were included with newly identified articles in the 2010 evidence report.

Decisions were made on the basis of a systematic grading of the quality of evidence and strength of recommendations as well as expert consensus when definitive data were not available. Results of the literature review were presented in evidence tables and published in the final evidence report.

American Academy of Pediatrics (AAP) Methods

Subcommittee members evaluated pertinent articles for quality of methodology and importance of results. Selected articles used in the AHRQ review were also reevaluated for their quality.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

In June 2009, the American Academy of Pediatrics (AAP) convened a new subcommittee to review and revise the May 2004 acute otitis media (AOM) guideline. The subcommittee comprised primary care physicians and experts in the fields of pediatrics, family practice, otolaryngology, epidemiology, infectious disease, emergency medicine, and guideline methodology.

Conclusions were based on the consensus of the subcommittee after the review of newer literature and reevaluation of the Agency for Healthcare Research and Quality (AHRQ) evidence. Key action statements were generated using BRIDGE-Wiz (Building Recommendations in a Developers Guideline Editor), an interactive software tool that leads guideline development through a series of questions that are intended to create a more actionable set of key action statements. BRIDGE-Wiz also incorporates the quality of available evidence into the final determination of the strength of each recommendation.

Rating Scheme for the Strength of the Recommendations

Definitions for Evidence-Based Statements

Statement	Definition	Implication
Strong recommendation	A strong recommendation in favor of a particular action is made when the anticipated benefits of the recommended intervention clearly exceed the harms (as a strong recommendation against an action is made when the anticipated harms clearly exceed the benefits) and the quality of the supporting evidence is excellent. In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain and the anticipated benefits strongly outweigh the harms.	Clinicians should follow a strong recommendation unless a clear and compelling rationale for an alternative approach is present.
Recommendation	A recommendation in favor of a particular action is made when the anticipated benefits exceed the harms but the quality of evidence is not as strong. Again, in some clearly identified circumstances, recommendations may be made when high-quality evidence is impossible to obtain but the anticipated benefits outweigh the harms.	Clinicians would be prudent to follow a recommendation but should remain alert to new information and sensitive to patient preferences.
Option	Options define courses that may be taken when either the quality of evidence is suspect or carefully performed studies have shown little clear advantage to 1 approach over another.	Clinicians should consider the option in their decision-making, and patient preference may have a substantial role.
No recommendation	No recommendation indicates that there is a lack of pertinent published evidence and that the anticipated balance of benefits and harms is presently unclear.	Clinicians should be alert to new published evidence that clarifies the balance of benefit versus harm.

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

External Peer Review

Internal Peer Review

Description of Method of Guideline Validation

After thorough review by the Subcommittee on Diagnosis and Management of Acute Otitis Media, a draft was reviewed by other AAP committees and sections, selected outside organizations, and individuals identified by the subcommittee as experts in the field. Additionally, members of the subcommittee were encouraged to distribute the draft to interested parties in their respective specialties. All comments were reviewed by the writing group and incorporated into the final guideline when appropriate.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is specifically stated for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Accurate diagnosis and appropriate treatment of a child presenting with acute otitis media (AOM)

For benefits of specific interventions considered in the guideline, see the "Major Recommendations" field.

Potential Harms

Diagnosis

- May miss acute otitis media (AOM) that presents with a combination of mild bulging, intense erythema, or otalgia that may not necessarily represent less severe disease and may also benefit from intervention
- Overdiagnosis of AOM
- Reduced precision in diagnosis
- Cost of tympanometry
- Need to acquire or reacquire skills in pneumatic otoscopy and tympanometry for some clinicians

Management

- Potential medication adverse effects
- Variable efficacy of some modes of treatment

Treatment with Antibiotics

- Adverse events attributable to antibiotics, such as diarrhea, diaper dermatitis, and allergic reactions
- Overuse of antibiotics leads to increased bacterial resistance
- Cost of antibiotics
- *Initial observation*: Possibility of needing to start antibiotics in 48 to 72 hours if the patient continues to have symptoms. Minimal risk of adverse consequences of delayed antibiotic treatment. Potential increased phone calls and doctor visits.
- Amoxicillin ineffective against β-lactamase–producing organisms
- Adverse effects of amoxicillin
- Cost and time of change in therapy
- Potential need for parenteral medication
- Possible small increase in episodes of AOM without anaphylaxis

Treatment with Tympanostomy

- Risks of anesthesia or surgery
- Cost
- Scarring of tympanic membrane (TM), chronic perforation, cholesteatoma
- Otorrhea

Prevention

- Potential vaccine side effects
- Cost of vaccine

- Requires annual immunization for influenza

Contraindications

Contraindications

- Any contraindication to anesthesia and surgery for tympanostomy tubes
- See the Centers for Disease Control and Prevention (CDC) guideline on contraindications to the influenza vaccine (http://www.cdc.gov/flu/professionals/acip/shouldnot.htm).

Qualifying Statements

Qualifying Statements

- The recommendations in this guideline do not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.
- This clinical practice guideline is not intended as a sole source of guidance in the management of children with acute otitis media. Rather, it is intended to assist primary care clinicians by providing a framework for clinical decision making. It is not intended to replace clinical judgment or establish a protocol for all children with this condition. These recommendations may not provide the only appropriate approach to the management of this problem.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Staying Healthy

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Lieberthal AS, Carroll AE, Chonmaitree T, Ganiats TG, Hoberman A, Jackson MA, Joffe MD, Miller DT, Rosenfeld RM, Sevilla XD, Schwartz RH, Thomas PA, Tunkel DE. The diagnosis and management of acute otitis media. Pediatrics. 2013 Mar;131(3):e964-99. [275 references] PubMed

Adaptation

Not applicable: The guideline was not adapted from another source.

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Subcommittee on Diagnosis and Management of Acute Otitis Media

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Financial Disclosures/Conflicts of Interest

All authors have filed conflict of interest statements with the American Academy of Pediatrics. Any conflicts have been resolved through a process approved by the Board of Directors.

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Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Pediatrics 2004 May;113(5):1451-65.

All clinical practice guidelines from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

Guideline Availability

Electronic copies: Available from the American Academy of Pediatrics (AAP) Policy Web site .

Print copies: Available from American Academy of Pediatrics, 141 Northwest Point Blvd., P.O. Box 927, Elk Grove Village, IL 60009-0927.

Availability of Companion Documents

The following is available:

- Shekelle PG, Takata G, Newberry SJ, et al. Management of acute otitis media: update. Evidence Report/Technology Assessment No. 198. Rockville (MD): Agency for Healthcare Research and Quality; 2010. Electronic copies: Available in Portable Document Format (PDF) from the Agency for Healthcare Research and Quality (AHRQ) Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI on June 8, 2004. The information was verified by the guideline developer on July 6, 2004. This NGC summary was updated on May 3, 2005 following the withdrawal of Bextra (valdecoxib) from the market and the release of heightened warnings for Celebrex (celecoxib) and other nonselective nonsteroidal anti-inflammatory drugs (NSAIDs). This NGC summary was updated by ECRI on June 16, 2005, following the U.S. Food and Drug Administration advisory on COX-2 selective and non-selective non-steroidal anti-inflammatory drugs (NSAIDs). This NGC summary was updated by ECRI Institute on October 3, 2007 following the U.S. Food and Drug Administration (FDA) advisory on Rocephin (ceftriaxone sodium). This NGC summary was updated by ECRI Institute on April 14, 2013. This summary was updated by ECRI Institute on February 15, 2017 following the U.S. Food and Drug Administration advisory on general anesthetic and sedation drugs.

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